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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EVERETT LABORATORIES, INC.,

Plaintiff,

v.

ACELLA PHARMACEUTICALS, LLC,

Defendant.

Civil Action No. _____

Hon. _____ U.S.D.J.

COMPLAINT FOR PATENT INFRINGEMENT AND JURY DEMAND

(Document Filed Electronically)

Plaintiff Everett Laboratories, Inc. ("Everett"), by its undersigned attorneys, for its Complaint against Defendant Acella Pharmaceuticals, LLC ("Acella" or "Defendant"), alleges as follows:

INTRODUCTION AND SUMMARY

1. This action seeks redress for, *inter alia*, Acella's deliberate and willful infringement of U.S. Patent No. 8,617,617 (the "'617 Patent") (a copy of which is attached as **Exhibit A** hereto) through Acella's manufacture, use, marketing, offering for sale, selling, and/or importing of its prescription-only nutritional supplement called "PNV-OB with DHA," which is a willful exact copy of Everett's "Vitafol®-OB + DHA" prescription-only nutritional supplement that is covered by the '617 Patent.

2. According to its product insert, PNV-OB with DHA contains the same vitamins and minerals, in the same amounts, as Everett's Vitafol®-OB + DHA. Accordingly—and as confirmed by a comparison of the PNV-OB with DHA product insert to the claims of the '617 Patent—PNV-OB with DHA directly infringes Claims 1-6, 12-13, 15-17, and 19-26 of the '617 Patent. Additionally, because Acella sells and distributes PNV-OB with DHA with a product insert that instructs the method of using and co-administering PNV-OB with DHA to provide nutritional supplementation to a patient, Acella is also inducing infringement of the foregoing Claims by patients, physicians and/or pharmacists.

3. On information and belief, leading computerized drug databases (such as First DataBank) have "linked" PNV-OB with DHA to Vitafol®-OB + DHA. This causes wholesalers that utilize information from the drug databases to offer Acella's lower-priced copy product PNV-OB with DHA as a substitute for Everett's branded Vitafol®-OB + DHA product. This also causes pharmacies that utilize information from the drug databases to substitute Acella's lower-priced copy product PNV-OB with DHA for Everett's branded Vitafol®-OB + DHA product when presented with a prescription for Vitafol®-OB + DHA. As a result, Everett is and will continue to be irreparably harmed as a result of the existence of the infringing PNV-OB with DHA product in the market.

4. The presence of the PNV-OB with DHA product in the market creates a huge dilemma—a "Hobson's Choice" for Everett. Either Everett stops marketing its Vitafol®-OB + DHA product or continues to spend money to market it to the advantage of its infringing competitor, Acella. Yet, if Everett stops marketing Vitafol®-OB + DHA, Everett will forfeit sales to other nutritional supplement companies which, unlike Everett, will still have an incentive to market and promote their products to doctors.

JURISDICTION AND VENUE

5. This Court has original and exclusive jurisdiction of this action, pursuant to 28 U.S.C. §§ 1331 and 1338(a), because the action arises under the Patent Laws of the United States, Title 35, United States Code. The Court also has original jurisdiction over the copyright infringement claim stated herein, pursuant to 28 U.S.C. § 1338(b), because that claim arises under Section 501(a) of the Copyright Act, 17 U.S.C. § 501(a). This Court further has supplemental jurisdiction pursuant to 28 U.S.C. § 1367(a) over the claim for tortious interference under New Jersey common law stated herein, because that claim forms part of the same case or controversy as the other claims stated herein.

6. The Court has personal jurisdiction over Defendant Acella in this action because Defendant regularly conducts business in New Jersey, has engaged in infringing acts in New Jersey, and specifically has offered to sell, offers to sell, has sold, and/or sells the product that is the subject of this Complaint in New Jersey and in this judicial district.

7. Venue is proper in this judicial district under 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to this Complaint occurred in this judicial district.

THE PARTIES

8. Everett is a corporation organized and existing under the laws of the State of New

Jersey, having its headquarters and principal place of business at One Main Street, Suite 203, Chatham, New Jersey, 07928.

9. Upon information and belief, Acella is a Delaware limited liability company, having its principal place of business at 11675 Great Oaks Way, Suite 144, Alpharetta, GA 30022.

STATEMENT OF FACTS

Plaintiff Everett Laboratories, Inc.

10. Plaintiff Everett is a pharmaceutical company that has been marketing and selling and continues to market and sell various prescription-only nutritional supplement products throughout the United States. Everett's reputation has been and continues to be enviable both in the trade and to the general consuming public in the United States. Everett is well known to prescribers of prescription-only nutritional supplements and medicines as well as to retailers, wholesalers, physicians, pharmacists, patients, and distributors in the industry in the United States.

Everett's Vitafol®-OB + DHA Product

11. Since February 2007, Everett has continuously and actively engaged in selling a nutritional supplement called Vitafol®-OB + DHA, which was formulated to deliver essential vitamins and minerals to the mother and her developing fetus. The caplet component of Vitafol®-OB + DHA contains specified quantities of vitamins A, D, C, E, folic acid, B_1, B_2, B_6, B_{12}, and niacin; and minerals calcium, iron, magnesium, zinc, and copper. *See* Vitafol®-OB + DHA package/product insert attached hereto as **Exhibit B**. It also contains a softgel capsule containing, *inter alia*, DHA from algae. *Id.*

12. Vitafol®-OB + DHA is a "branded product." The U.S. Food and Drug Administration ("FDA") regulates "branded" drugs. Although prescription-only multivitamins

are not regulated like drugs are by the FDA, the parallels are similar and hence this Complaint uses the term "branded" to refer to Everett's innovator products.

13. On December 31, 2013, the U.S. Patent and Trademark Office issued the '617 Patent (**Exhibit A** hereto) for the product formulation of Vitafol®-OB + DHA.

14. Claim 1 of the '617 Patent recites the following:

> 1. A kit comprising a first composition consisting of vitamin A, vitamin D, vitamin C, vitamin E, folic acid, vitamin B_1, vitamin B_2, vitamin B_6, vitamin B_{12}, niacin, calcium, iron, magnesium, zinc, copper and one or more pharmaceutically acceptable carriers and a second composition consisting of omega-3 fatty acids and one or more pharmaceutically acceptable carriers.

15. The named inventors of the '617 Patent are John A. Giordano and Charles J. Balzer, who have assigned their rights in the '617 Patent to Everett, such that Everett is the assignee and owner of the '617 Patent.

16. Everett has engaged in extensive advertising and promotion of Vitafol®-OB + DHA to gain goodwill and public recognition of its product. To that end, Everett has spent substantial sums of money and resources to develop, advertise, and market Vitafol®-OB + DHA.

17. Everett has caused Vitafol®-OB + DHA to be listed in online drug databases that pharmacies use in filling prescriptions for nutritional supplements, including the leading drug databases of First DataBank and Medi-Span, as well as Gold Standard.

Defendant Acella

18. Acella is a Delaware limited liability company with offices in Alpharetta, Georgia. On information and belief, its business model includes formulating alternatives or substitutes for existing branded vitamin products and offering them for sale at lower prices.

19. Acella directly competes with Everett in the market for prescription-only nutritional supplements containing DHA.

Acella's PNV-OB with DHA Product

20. Upon information and belief, Acella uses, manufactures, markets, offers for sale, imports, and/or sells PNV-OB with DHA, which is a copy of, and hence competes directly with, Everett's Vitafol®-OB + DHA product. A copy of the package insert for PNV-OB with DHA is attached as **Exhibit C** hereto. Acella sells its PNV-OB with DHA copy of Everett's Vitafol®-OB + DHA product at a significantly lower price than Everett's Vitafol®-OB + DHA product. Upon information and belief, Acella offers for sale and has sold or caused to be sold its lower-cost PNV-OB with DHA copy product in this judicial district.

21. According to the PNV-OB with DHA package insert, and as shown in the following Chart 1, PNV-OB with DHA directly infringes Claim 1 of the '617 Patent, as it contains the same vitamins and minerals listed in Claim 1 of the ' 617 Patent:

CHART 1

'617 Patent, Claim 1 Ingredients	Vitafol®-OB + DHA	PNV-OB with DHA
vitamin A	included	included
folic acid	included	included
vitamin B_1	included	included
vitamin B_2	included	included
niacin	included	included
vitamin B_6	included	included
calcium	included	included
vitamin B_{12}	included	included
vitamin C	included	included
vitamin D	included	included
vitamin E	included	included
iron	included	included
magnesium	included	included
zinc	included	included
copper	included	included
and one or more pharmaceutically acceptable carriers	has at least one pharmaceutically acceptable carrier	has at least one pharmaceutically acceptable carrier
second composition consisting of omega-3 fatty acids and	included	included
one or more pharmaceutically	has at least one	has at least one

'617 Patent, Claim 1 Ingredients	Vitafol®-OB + DHA	PNV-OB with DHA
acceptable carriers	pharmaceutically acceptable carrier	pharmaceutically acceptable carrier

22. PNV-OB with DHA also directly infringes Claims 2-6, 12-13, 15-17, and 19-26 of the '617 Patent.

23. Additionally, because Acella sells and distributes PNV-OB with DHA with a package insert that instructs the method of using the PNV-OB with DHA kit to provide nutritional supplementation to the patient, Acella is also inducing direct infringement of the aforementioned claims of the '617 Patent by the patients, physicians and/or administering pharmacists.

Linking And Automatic Substitution By Drug And Nutritional Supplement Databases

24. Computerized drug databases (also known as compendia)—such as First DataBank, Medi-Span, and Gold Standard—link non-branded copy products to branded products by comparing the key active ingredients of each product. If the products match in terms of type, content, and amount of the key ingredients considered by the database, the products will be linked. If products are linked, there is typically automatic substitution by the pharmacies that are asked to fill the prescription by the copy product with the lower price. Indeed, many insurance companies and other third-party payers insist that the cheaper, copy product be substituted for the branded product.

25. First DataBank and Medi-Span categorize products for purposes of determining substitutability based upon labeling provided to them by manufacturers. Their customers include retail pharmacy chains, drug wholesalers, health management organizations, insurance companies, and Medicaid state agencies. These customers purchase data from First DataBank and Medi-Span for use in their own computer database systems (such as databases utilized by

pharmacists at retail pharmacies). These data support pharmacy dispensing, formulary management, drug pricing analysis, and electronic prescribing. Most major retail pharmacies and pharmacy chains rely on data provided by First DataBank or Medi-Span to assist the pharmacist in making dispensing decisions about prescription products. Specifically, First DataBank data is utilized by Rite Aid®, CVS®, CVS Caremark®, Safeway®, Publix®, and Costco® pharmacy chains, and Medi-Span data is utilized by Walgreens® and Wal-Mart® pharmacy chains.

26. First DataBank and Medi-Span obtain data about new pharmaceutical products directly from the products' manufacturers and/or distributors. Prior to the launch of a new product, manufacturers and/or distributors submit new product information to First DataBank and Medi-Span. This information includes labels, product inserts or package inserts, and other promotional materials that describe the product's ingredients, strength, dosage form, route of administration, and price.

27. Neither First DataBank nor Medi-Span performs or sponsors any independent testing of pharmaceutical products. Both databases rely strictly on information provided to them by product manufacturers and/or distributors concerning their products.

28. When First Databank first receives information about a new pharmaceutical product, it is reviewed by a research associate in the Editorial Services Department. The research associate will identify the product's key active ingredients and their strength, the dosage form, and the route of administration. If an existing product with the same key active ingredients in the same strengths, in the same dosage form, and with the same route of administration is found within the First DataBank database, the research associate will assign the new product to the same clinical formulation ID (also known as the "Generic Code Number" or "GCN code") as that assigned to the existing product in the database. The clinical formulation ID is the newly-

formed identifier name for what was previously known as the Generic Code Number. Products which have the same GCN code are considered pharmaceutically equivalent to each other. Products having the same GCN code are also described as being "linked." If more than one product is assigned to the same GCN code, those products are described as "multiple source" products, *i.e.*, they are pharmaceutically equivalent products that are available from multiple sources.

29. Medi-Span has an analog to First DataBank's GCN code, which Medi-Span refers to as the "Generic Product Identifier" or "GPI code." Products assigned to the same GPI code in the Medi-Span database have the same key active ingredients in the same strengths, in the same dosage form, with the same route of administration, and are also considered pharmaceutically equivalent to each other. Products having the same GPI code are also said to be "linked."

30. When pharmacists at the retail pharmacies that utilize First DataBank and Medi-Span data process prescriptions written by doctors for Everett's Vitafol®-OB + DHA nutritional supplement product, they will substitute defendant Acella's PNV-OB with DHA nutritional supplement product for Everett's Vitafol®-OB + DHA nutritional supplement product to the extent those products are linked in the First DataBank and Medi-Span databases.

31. Pharmacists will make substitutions in order to capitalize upon the lower price of Defendant Acella's PNV-OB with DHA generic copy product.

32. Everett's sales of its Vitafol®-OB + DHA product will therefore be displaced by sales of Defendant Acella's PNV-OB with DHA product, due to the linking of PNV-OB with DHA to Vitafol®-OB + DHA in the databases such as First DataBank as described hereinabove. Wholesalers rely upon the leading databases to provide them with information regarding which products are linked and therefore substitutable. Wholesalers recognize that linking will inevitably result in pharmacies substituting generic copy products (such as Acella's PNV-OB

with DHA) for branded products to which they are linked (such as Everett's Vitafol®-OB + DHA). Thus, the pharmacies will have less demand for the branded products (such as Everett's Vitafol®-OB + DHA) from wholesalers, and wholesalers will instead move to stock up on the generic copy products (such as Acella's PNV-OB with DHA), even prior to actual substitution occurring. Accordingly, wholesalers (to whom Everett makes substantially all of its sales of Vitafol®-OB + DHA) reduce their orders of branded products (such as Everett's Vitafol®-OB + DHA) in anticipation of the lower demand from pharmacies that results from pharmacies substituting generic copy products (such as Acella's PNV-OB with DHA) for branded products to which they are linked (such as Everett's Vitafol®-OB + DHA).

33. Everett's sales to wholesalers will continue to decrease as substitution by pharmacies increases and the related demand for Everett's branded, patented products (such as Vitafol®-OB + DHA) decreases. That is, in fact, how substitution at the pharmacy level affects Everett's sales. The pharmacies order fewer of Everett's branded, patented products from wholesalers, and wholesalers therefore order fewer of Everett's branded, patented products from Everett.

Drug Databases Are Linking PNV-OB with DHA To Vitafol®-OB + DHA

34. On information and belief, including based on certain "screen shot" evidence obtained by Everett, First DataBank is at least one specific leading drug database that is already "linking" PNV-OB with DHA to Vitafol®-OB + DHA in its database, which information is available to the wholesalers and pharmacies who utilize First DataBank data. Accordingly, when pharmacists at retail pharmacies that show PNV-OB with DHA as being linked to Vitafol®-OB + DHA fill a prescription for Vitafol®-OB + DHA, the pharmacists will substitute PNV-OB with DHA for Vitafol®-OB + DHA. Pharmacists will make those substitutions in order to capitalize upon the advantage of the significantly lower price of the Acella copy product, PNV-OB with

DHA. Wholesalers will decrease purchases of Everett's branded, patented Vitafol®-OB + DHA product in favor of purchases of Acella's PNV-OB with DHA generic copy product. Sales of Everett's branded, patented Vitafol®-OB + DHA product will therefore be displaced by sales of Acella's PNV-OB with DHA product due to the linking of the products.

Everett's Irreparable Harm From Acella's Infringing PNV-OB with DHA Product

35. On information and belief, Acella is currently selling and/or distributing its PNV-OB with DHA generic copy product to be sold through retail pharmacies, which, on information and belief, are and/or will be selling PNV-OB with DHA as a substitute for Vitafol®-OB + DHA.

36. Everett faces substantial and irreparable harm as a result of Acella's infringing sales of its PNV-OB with DHA product. As pharmacies substitute PNV-OB with DHA despite physicians' prescriptions having specified Vitafol®-OB + DHA, Everett loses sales to Acella based on reduced demand from wholesalers for Everett's Vitafol®-OB + DHA. Wholesalers anticipate reduced demand from pharmacies based on linking and begin reducing their orders accordingly in advance so they will not be left with excess product. Because wholesalers recognize that the linking of Acella's PNV-OB with DHA generic copy product to Everett's branded, patented Vitafol®-OB + DHA product will surely result in significant substitution, wholesalers act as first movers to begin reducing their orders from Everett and to instead stock up on Acella's generic copy product. The irreparable harm to Everett therefore actually precedes significant substitution at the pharmacy level, and only accelerates and worsens as actual substitution by pharmacies increases.

37. Additionally, in the health care industry, there is significant (if not absolute) pressure on pharmacists (by, for example, insurance companies) to substitute the lower-cost copy

version of a prescription drug or supplement for a higher-cost brand-name version, further rapidly increasing substitution and resulting in irreparable harm to Everett.

38. The irreparable harm to Everett is magnified by the long-term effects on Everett's business goodwill and the fact that pharmacies with significant supplies of Acella's PNV-OB with DHA generic copy product will be motivated to exhaust their supplies even after Everett has succeeded in ejecting PNV-OB with DHA from the marketplace through patent enforcement. After a pharmacy has stocked up on the copy product, the pharmacy will naturally want to use up its inventory rather than see it go to waste. The critical harm to Everett in the present circumstances is evident: it is virtually impossible to "put the genie back in the bottle" once a copyist competitor (such as Acella and its infringing PNV-OB with DHA product) is able to get a foothold in the marketplace. The realities of the marketplace will in this manner make it impossible for Everett to overcome Acella's infringing activities.

39. Everett is also suffering irreparable harm to its goodwill and reputation respecting its entire line of products, especially as physicians and pharmacists become accustomed to using Acella's generic copy products (such as PNV-OB with DHA) as substitutes for Everett's branded, patented products (such as Vitafol®-OB + DHA) and Everett's other nutritional supplement products. Everett's branded, patented products are not retail products, but are products prescribed by doctors and dispensed by pharmacists. Retail chains motivate their pharmacists to sell cheaper copy versions whenever possible. Over time, habits develop, and pharmacists associate Everett's branded, patented products and Everett's other products with cheaper copy versions. It is critical to Everett's business that pharmacists and doctors do not associate Everett's products with cheaper copy versions, and that pharmacists do not routinely substitute Acella's generic copy products for Everett's branded, patented products (such as Vitafol®-OB + DHA). As a result of Acella's infringement, Everett will therefore suffer

irreparable harm to its goodwill and reputation respecting its entire line of products (including Select-OB®+DHA, Vitafol®-PN, Vitafol®-One, and Strovite® One), especially as pharmacists become accustomed to using PNV-OB with DHA as a substitute for Vitafol®-OB + DHA.

40. Moreover, Vitafol®-OB + DHA and PNV-OB with DHA are not the only prescription-only nutritional supplements in the U.S. market. Vitafol®-OB + DHA is not a retail product, but a product prescribed by doctors and dispensed by pharmacists. By having an innovative product and visiting thousands of doctors and spending significant sums in marketing and promotional efforts, Everett has created a brand awareness and excellent reputation for Vitafol®-OB + DHA commensurate with and because of the patented inventions it incorporates. However, to remain effective it is necessary that Everett continue to market and promote Vitafol®-OB + DHA to prescribing doctors, so that they do not pass over Vitafol®-OB + DHA in favor of some other nutritional supplement when writing prescriptions for their patients.

41. Accordingly, not only will Everett lose substantial sales and market share because of substitution of Acella's PNV-OB with DHA generic copy product for Everett's branded, patented Vitafol®-OB + DHA product at the pharmacy level (such that Everett will continue to lose sales to wholesalers at an ever-increasing rate as linking of Acella's PNV-OB with DHA generic copy product to Everett's branded, patented Vitafol®-OB + DHA product further expands and as time simply passes while the products are linked such that substitutions increasingly occur), but Everett also risks losing its goodwill and reputation respecting its entire line of products with pharmacists and doctors.

42. The presence of the PNV-OB with DHA product in the market creates a huge dilemma—a "Hobson's Choice" for Everett. Either Everett stops marketing the Vitafol®-OB + DHA product or continues to spend money to market Vitafol®-OB + DHA to the advantage of its infringing competitor, Acella. Yet, if Everett stops marketing Vitafol®-OB + DHA, Everett

will forfeit sales to other nutritional supplement companies which, unlike Everett, will still have an incentive to market and promote their products to doctors. Moreover, it will not be possible to calculate how many such sales Everett will have lost to other sellers of prescription-only nutritional supplements.

Everett's Further Irreparable Harm From Acella's Coordinated Infringement of Everett's Four Most Successful Products

43. The irreparable harm to Everett is even further magnified by Acella's intentional and malicious course of conduct in infringingly copying not only Everett's patented Vitafol®-OB + DHA product with Acella's PNV-OB with DHA product and getting the product linked to cause substitution and displacement of sales of Everett's patented Vitafol®-OB + DHA product, but also simultaneously linking Acella's infringing copy products of PNV-First, Choice-Tabs, and Choice-OB + DHA to Everett's branded, patented nutritional supplement products of Vitafol®-One (covered by U.S. Patent No. 8,183,227), Strovite® One (covered by U.S. Patent No. 6,863,904), and Select-OB® + DHA (covered by U.S. Patent Nos. 8,609,629 and 8,197,855), respectively, to cause massive substitution and displacement of sales of those of Everett's branded, patented products as well.

44. Acella's achievement of linking its four generic copy products discussed herein (*i.e.*, Choice-OB + DHA, PNV-First, Choice-Tabs, and PNV-OB with DHA, collectively hereafter "Acella's Generic Copy Products") to Everett's four corresponding copied products that are branded and patented (*i.e.*, Select-OB®+DHA, Vitafol®-One, Strovite® One, and Vitafol®-OB + DHA, collectively hereafter "Everett's Branded, Patented Products"), respectively, on information and belief, occurred in close proximity in time shortly before the linking was discovered by Everett in approximately early June of 2013.

45. Everett's Branded, Patented Products together comprise approximately 87% of its total company sales. Acella's combined attacks will therefore result in Everett losing more than

90% of its sales of the four products that account for approximately 87% of its total sales (equaling approximately 78.3% of Everett's total sales). With all four of Everett's Branded, Patented Products subject to a coordinated linking effort by Acella—and therefore all subject to the same types of irreparable harm described above with respect to Vitafol®-OB + DHA specifically—Everett's overall irreparable harm is even further compounded and magnified in terms of lost sales, market share, and related goodwill for all the same reasons described above with respect to Vitafol®-OB + DHA specifically.

46. Everett thus faces the "Hobson's choice" described above with respect to all four of Everett's Branded, Patented Products at the same time—a truly pernicious form of irreparable harm. If Everett continues to spend money to market and make available Everett's Branded, Patented Products, it will be only building up the sales of the infringing Acella's Generic Copy Products. However, if Everett discontinues Everett's Branded, Patented Products, it will relinquish the opportunity to maintain and expand the market share of Everett's Branded, Patented Products in the market for nutritional supplements, and will lose all of its sales to other competitors. With this dilemma applying to all of Everett's Branded, Patented Products, the damage becomes absolute. It is a "no-win" situation for Everett that is harming and will continue to harm Everett irreparably.

47. Acella is brazenly attempting to rapidly displace nearly all of Everett's sales so that it can either acquire Everett's patented and trademarked product lines (similar to what Acella previously did to acquire the trademark rights to the "Prenate®" line of products) or to destroy Everett's business and thereby open the market for Acella's sister company (Avion Pharmaceuticals, LLC) that competes with Everett in the sale of branded nutritional supplements.

48. Everett has already filed and served five other separate lawsuits against Acella for, among other things, patent infringement of the patents covering its Vitafol®-One product

(covered by U.S. Patent No. 8,183,227), Strovite One (covered by U.S. Patent No. 6,863,904), Select-OB®+DHA product (covered by U.S. Patent Nos. 8,197,855 and 8,609,629), and Vitafol®-OB+DHA product (covered by U.S. Patent Nos. 6,814,983 and 7,390,509). Those five separate actions are titled *Everett Laboratories, Inc. v. Acella Pharmaceuticals, LLC*, Civil Action No. 1:13-cv-03470-JEI-KMW (D.N.J.), *Everett Laboratories, Inc. v. Acella Pharmaceuticals, LLC*, Civil Action No. 1:13-cv-03487-JEI-KMW (D.N.J.), *Everett Laboratories, Inc. v. Acella Pharmaceuticals, LLC*, Civil Action No. 1:13-cv-03529-JEI-KMW (D.N.J.), *Everett Laboratories, Inc. v. Acella Pharmaceuticals, LLC*, Civil Action No. 1:13-cv-04294-JEI-KMW (D.N.J.), and *Everett Laboratories, Inc. v. Acella Pharmaceuticals, LLC*, Civil Action No. 1:13-cv-07603-JEI-KMW (D.N.J.), and the complaints in those actions and all allegations of those complaints are incorporated herein by reference.

Copyright Registration of Everett's Product Insert for Vitafol®-OB + DHA

49. Everett's Vitafol®-OB+DHA product is sold with a package/product insert authored by Everett (Everett's "Vitafol®-OB + DHA product insert"), the original version of which is attached as **Exhibit B**. Everett's Vitafol®-OB + DHA product insert has provided and continues to provide information about the vitamins and minerals of Vitafol®-OB + DHA, as well as substantial other information pertaining to the use of Vitafol®-OB + DHA. Everett has registered its copyrights in the Vitafol®-OB + DHA product insert, specifically by registering the original version (which registration, *i.e.*, United States Copyright Office Registration No. TX 6-584-656, is reflected in **Exhibit D** attached hereto).

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

(Infringement Of The '617 Patent)

50. To the extent not inconsistent with the allegations herein, or in the alternative, Everett refers to and incorporates herein the allegations of the foregoing Paragraphs 1-49, the

same as if set forth at length.

51. Everett is the assignee and owner of the '617 Patent (which patent was duly and legally issued by the PTO on December 31, 2013).

52. Upon information and belief, Defendant has, through the conduct described above, engaged in the manufacture, use, sale, offer for sale, and/or importation of products that infringed and continue to infringe, directly and/or indirectly by contributorily infringing and/or inducing to infringe, one or more of the claims of the '617 Patent, in violation of 35 U.S.C. § 271 and without Everett's authority. The infringing product is Defendant's PNV-OB with DHA prescription multivitamin product.

53. Defendant's willful acts of infringement are causing damages and irreparable harm to Everett and will continue to cause damages and irreparable harm unless enjoined by this Court.

SECOND CLAIM FOR RELIEF
(Copyright Infringement)

54. To the extent not inconsistent with the allegations herein, or in the alternative, Everett refers to and incorporates herein the allegations of the foregoing Paragraphs 1-53, the same as if set forth at length.

55. This cause of action arises under the federal Copyright Act, 17 U.S.C. §§ 101, *et seq.* The Court has original jurisdiction over this matter pursuant to Everett's filing of, and the federal Copyright Office's subsequent issuance of, a copyright registration certificate covering Everett's Vitafol®-OB + DHA product insert. A true and correct copy of the certificate specifically registering the copyrights for the original product insert for Everett's Vitafol®-OB + DHA is attached hereto as **Exhibit D** (United States Copyright Office Registration No. TX 6-584-656).

56. Everett is the sole owner of all copyright rights in the Vitafol®-OB + DHA product insert and all corresponding text, layout, and other elements of expression encompassed therein, including the selection and arrangement of text and other elements of expression. The Vitafol®-OB + DHA product insert is original. Further, the U.S. Copyright Office issued Certificates of Registration identifying Everett as the copyright author and therefore owner. *See* **Exhibit D**.

57. Defendant has infringed Everett's copyrights in the Vitafol®-OB + DHA product insert. Defendant has, among other things, copied, distributed, used, sold, displayed, and distributed virtually all of the Vitafol®-OB + DHA product insert without approval or authorization from Everett.

58. Defendant had access to and copied copyright-protected elements of the Vitafol®-OB + DHA product insert to create Defendant's infringing PNV-OB with DHA package insert.

59. Defendant's acts as alleged herein constitute copyright infringement under the U.S. Copyright Act, 17 U.S.C. § § 101, *et seq.* By its actions alleged above, Defendant has intentionally and willfully infringed, and will continue to intentionally and willfully infringe, Everett's copyrights in the Vitafol®-OB + DHA product insert.

60. As a direct and proximate result of Defendant's unlawful acts of copyright infringement as set forth above, Everett has suffered and will continue to suffer injury to its business, goodwill, and property in an amount not presently known. Everett is entitled to recover from Defendant the damages it has sustained and will sustain as a result of Defendant's unlawful acts of copyright infringement as alleged herein, pursuant to 17 U.S.C. § 504. Everett is further entitled to recover from Defendant the gains, profits, and advantages that Defendant has obtained as a result of the wrongful conduct alleged herein, pursuant to 17 U.S.C. § 504. Everett at

present is unable to ascertain the full extent of its damage, or the gains, profits and advantages that Defendant has obtained by reason of the wrongful conduct described herein.

61. Alternatively, as Everett's copyright registration was issued before the infringement occurred, Everett may elect to seek statutory damages under 17 U.S.C. § 504(c) for Defendant's unlawful and willful acts of copyright infringement as set forth above.

62. Everett is also entitled, pursuant to 17 U.S.C. § 502, to an order for injunctive relief that prevents and restrains Defendant from continuing to infringe on the Vitafol®-OB + DHA product insert and, pursuant to 17 U.S.C. § 503, to an order impounding any and all of Defendant's products that contain the infringing PNV-OB with DHA package insert. Everett is further entitled to an order compelling Defendant to recall and retrieve and all of Defendant's products that contain the infringing PNV-OB with DHA package insert that are in the marketplace. Everett has no adequate remedy at law for Defendant's wrongful and unlawful conduct because, among other things: (a) Everett's copyrights in its Vitafol®-OB + DHA product insert are unique and valuable property which have no readily determinable market value; (b) Defendant's infringement harms Everett such that Everett could not be made whole by any monetary award for such infringement; and (c) Defendant's wrongful and unlawful conduct, and the resulting damage and harm to Everett, is continuing and irreparable.

THIRD CLAIM FOR RELIEF
(Tortious Interference Under New Jersey Common Law)

63. To the extent not inconsistent with the allegations herein, or in the alternative, Everett refers to and incorporates herein the allegations of the foregoing Paragraphs 1-62, the same as if set forth at length.

64. Acella's conduct as aforesaid constitutes tortious interference under the common law of the State of New Jersey.

65. By virtue of Everett's patent rights covering Everett's Branded, Patented Products

as described above, Everett has and has had a protectable right in the prospective economic or contractual relationships flowing from its marketing and selling of Everett's Branded, Patented Products, and a reasonable expectation of economic advantage related thereto.

66. Acts of Defendant have intentionally and maliciously interfered with Everett's protectable rights in the prospective economic or contractual relationships and/or reasonable expectation of economic advantage derived from Everett's patent rights in the seven patents covering Everett's Branded, Patented Products. Defendant intentionally and maliciously entered Everett's exclusive markets guaranteed by these patents in a coordinated attack, thereby depriving Everett of the value of its patent rights and the economic advantages they protect.

67. Despite its knowledge of Everett's patent rights, Defendant entered Everett's exclusive markets intentionally and without justification or excuse by introducing all of Acella's Generic Copy Products that infringe the five patents. By its actions, Defendant has sought to harm and has harmed Everett and its business interests and prospective economic advantages.

68. Defendant's wrongful and unlawful conduct was the reasonable, foreseeable, and proximate cause of Everett's loss of the prospective economic gain promised by the prospect of Everett's continued exclusive markets guaranteed by its patent rights. Defendant's interference has thus caused and is causing Everett's loss of prospective gain.

69. In absence of Defendant's entry into Everett's exclusive markets guaranteed by its patent rights covering Everett's Branded, Patented Products, there is a reasonable probability that Everett would have received the anticipated economic advantages and benefits flowing therefrom which have been and are being captured by Acella.

70. Defendant's unlawful entry into the exclusive markets covered by Everett's patent rights covering Everett's Branded, Patented Products has undermined and is undermining Everett's position in the markets and has caused and is causing Everett to suffer significant,

irreparable economic and reputational harms as a result. Everett has suffered and will continue to suffer both monetary damages and other damages in the form of lost sales, lost market share, lost business opportunities, lost prospective economic advantage, and lost goodwill, all contributing to irreparable harm for which Everett has no adequate remedy at law. Everett is entitled to recover its damages, and further to recover punitive or exemplary damages based on Defendant's actual malice in an amount appropriate to punish and to make an example of Defendant to the community.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Everett Laboratories, Inc. asks that this Court enter judgment against Defendant Acella Pharmaceuticals, LLC, granting the following relief:

A. Judgment that Defendant has directly infringed U.S. Patent No. 8,617,617.

B. Judgment that Defendant has indirectly infringed U.S. Patent No. 8,617,617 by inducing the direct infringement of the '617 Patent.

C. Judgment that Defendant has indirectly infringed U.S. Patent No. 8,617,617 by contributing to the direct infringement of the '617 Patent.

D. That Defendant be held to have willfully engaged in copyright infringement in violation of Section 501 of the Copyright Act, 17 U.S.C. § 501.

E. That a preliminary and permanent injunction issue prohibiting Defendant and its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them, from further direct and/or indirect copyright infringement of the Vitafol®-OB + DHA product insert.

F. That Defendant be required to:

1. Deliver upon oath, to be impounded during the pendency of this action, and for destruction pursuant to judgment herein, all PNV-OB with DHA products;

2. Seek and obtain a full recall of all PNV-OB with DHA products that have been sold, consigned, or placed into inventory of a wholesaler or retailer;

3. Place all revenues generated from the sale of PNV-OB with DHA, as well as all future payments from the sale of PNV-OB with DHA, in a trust account during the pendency of this action;

4. Issue a recall and retrieve all PNV-OB with DHA products and/or any nutritional supplements or any other of Defendant's products that bear or contain the infringing PNV-OB with DHA product insert, or any other material that infringes on Everett's Vitafol®-OB + DHA product insert, that are being or have been used, advertised, marketed, offered, distributed, or sold in the marketplace; and

5. Deliver upon oath, to be impounded during the pendency of this action, and for destruction pursuant to judgment herein, any and all PNV-OB with DHA package inserts and any other of Defendant's materials that infringe on Everett's copyright.

G. That Defendant be required to file with the Court and serve on Everett, within 30 days after service of the Court's Order as herein prayed, a report in writing under oath stating in detail the manner and form in which Defendant has complied with the Court's Order.

H. Judgment that Defendant be held liable for tortious interference under New Jersey common law.

I. That Defendant be required to account for and pay over to Everett all profits obtained by Defendant from its violations of law complained of herein.

J. That the Court grant a preliminary and permanent injunction enjoining Acella from manufacturing, marketing or selling, importing, or offering for sale, PNV-OB with DHA.

K. That the Court grant a preliminary and permanent injunction enjoining Acella from making claims that would cause PNV-OB with DHA to be listed as interchangeable with, or a substitute for, Vitafol®-OB + DHA.

L. That the Court order Acella to pay compensatory damages to Everett in an amount to be determined at trial.

M. That the Court order Defendant to pay Everett's damages and Defendant's profits pursuant to 17 U.S.C. § 504(b) for Defendant's willful infringement of Everett's copyright or, alternatively, if Everett elects, statutory damages pursuant to 17 U.S.C. § 504(c).

N. That Defendant pay Everett additional damages for willful infringement of the '617 Patent in an amount to be determined at trial pursuant to 35 U.S.C. § 284.

O. Judgment that this is an exceptional case under 35 U.S.C. § 285 and awarding Everett its costs, expenses and reasonable attorneys' fees incurred in this action.

P. Judgment awarding Everett punitive or exemplary damages in an amount appropriate to punish and to make an example of Defendant to the community.

Q. Judgment awarding Everett its full costs and reasonable attorneys' fees incurred in this action under Section 505 of the Copyright Act, 15 U.S.C. § 505.

R. That Defendant be ordered to pay prejudgment interest to Everett.

S. Such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38, Fed. R. Civ. P., Plaintiff Everett Laboratories, Inc. hereby demands a jury trial on all issues triable of right by a jury.

Respectfully submitted,

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Attorneys for Plaintiff
Everett Laboratories, Inc.

Dated: January 2, 2014.

CERTIFICATION OF NON-ARBITRABILITY

Pursuant to Local Civil Rule 201.1(d)(2), the undersigned attorneys for Plaintiff, Everett Laboratories, Inc., certify that this action is not eligible for arbitration under Local Civil Rule 201.1 because the relief sought in the Complaint primarily consists of a demand for preliminary and permanent injunctive relief, as well as damages believed to be in excess of $150,000.00, exclusive of interest, costs, and any claim for punitive damages, and involves complex issues of patent and copyright law.

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned attorney for Plaintiff, Everett Laboratories, Inc., certifies that, to the best of his knowledge, the matters in controversy are related to *Everett Laboratories, Inc. v. Acella Pharmaceuticals, LLC,* Case No. 1:13-cv-3529 (JEI)(KMW), and the State law cause of action pled herein is related to Case Nos. 1:13-cv-3470 (JEI)(KMW), 1:13-cv-3487 (JEI)(KMW), 1:13-cv-3529 (JEI)(KMW), 1:13-cv-4294 (JEI)(KMW), and 1:13-cv-7603 (JEI)(KMW) bearing the same title, all pending in the District of New Jersey.

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EVERETT LABORATORIES, INC.

By /s/ Robert J. Schoenberg

Dated: January 2, 2014.